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10/673,854	09/30/2003	Sudhir K. Sinha	P56884	2641

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,854

Applicant(s)

SINHA ET AL.

Examiner

Christopher M. Babic

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (1-12 and 24-26) in the reply filed on August 1, 2005 has been considered and deemed not persuasive. The traversal is on the ground(s) that there is no search burden on the Examiner. Applicants are correct in asserting that a *sequence search* of Claim 4 will include a *sequence search* of Claim 13. However, the textual based search of Claim 10 would encompass *any* polymerase chain reaction (PCR), as opposed to only *Alu* based PCR reactions as those in Claim 4. Furthermore, many oligonucleotide primers, as those presented in Claims 4 and 13, are not disclosed in nucleic acid databases and require a manual examination of suspected applicable references (i.e. primers).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3-8, 11, 25, and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 3, 5, 7, 25, and all claims dependent thereof, these claims are indefinite because it is unclear what is encompassed by the phrase, "an (*AluSTY_a/AluSTX_a*) locus". The instant specification makes no reference as to what sequence each locus is drawn to or where each locus is found in each respective (X/Y) chromosome. Furthermore, the use of the article "an" in front of the term "locus" implies that there is more than one (*AluSTY_a/AluSTX_a*) locus.

In addition, an initial search of the prior art indicates that the terms used for the Alu transposable elements in the instant application (i.e. *AluSTY_a/AluSTX_a*) are not equivalent to the generally accepted standardized nomenclature used for Alu repeats (See included reference: Batzer et al. "Standardized Nomenclature for Alu Repeats" Journal of Molecular Evolution. 1996. 42: Pages 3-6).

Due to the indefiniteness of the instant claims, an accurate and thorough search on the merits is not possible.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. ("Sexing of Human and Other Primate DNA" Biological Chemistry. October 1998. Vol. 379" Pages 1287-1288).

Regarding Claim 1, Wilson et al. disclose a method for determining gender from a human DNA sample, said method comprising: providing a human DNA sample (Figure 1, Lanes 2,3), said DNA sample containing X chromosomal material and potentially containing Y chromosomal material (Figure 1, Lanes 2,3); selecting at least one locus from a non-combining X-Y homologous region, said region containing a monomorphic *Alu* insertion in one of the X chromosome and the Y chromosome (Page 1287, Column 1, Paragraph 3); amplifying the selected locus of the DNA sample in an amplification reaction (Figure 1), wherein the product of the reaction is a mixture of amplified alleles from the amplified locus present in the sample (Figure 1); and determining the gender of the DNA sample by evaluating the amplified alleles in terms of size and number (Figure 1, Lanes 2,3).

Regarding Claim 2, Wilson et al. disclose PCR (Figure1).

Regarding Claim 10, Wilson et al. disclose fragment resolution on an agarose gel (Figure 1).

Regarding Claim 12, Wilson et al. disclose male gender characterized by two DNA fragments and female gender characterized by one DNA fragment (Figure 1, Lanes 2,3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. ("Sexing of Human and Other Primate DNA" Biological Chemistry. October 1998. Vol. 379" Pages 1287-1288) in view Schuum et al. (U.S. 5,843,660).

The methods of Wilson et al. have been outlined in the rejections above. Wilson et al. does not specifically disclose the use of covalently labeled fluorescent primers.

Schuum et al. disclose the use of covalently labeled fluorescent primers in multiplex amplification of short tandem repeat loci (Column 17, Lines 55-67; Columns 21-33, Examples 1-25).

Furthermore, Schuum et al. disclose that fluorescent detection is preferred over radioactive methods of labeling and detection, because it does not require the use of radioactive materials, and all the regulatory and safety problems which accompany the use of such material (Column 16, Lines 4-7).

Based on the disclosure of Schuum et al., one of ordinary skill in the art at the time of invention would have had a reasonable expectation of success practicing the methods of Wilson et al. with fluorescent primers. The motivation to do so, provided by

Schuum et al., would have been to circumvent the problems of using the radioactive labels. It would have been *prima facie* obvious to one of skill in the art at the time of invention to practice the methods as claimed.

1. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. ("Sexing of Human and Other Primate DNA" Biological Chemistry. October 1998. Vol. 379" Pages 1287-1288) in view of Wang et al. ("Quantitation of mRNA by the polymerase chain reaction" Proc. Natl. Acad. Sci. December 1989. Vol. 86: Pages 9717-9721).

The methods of Wilson et al. have been outlined in the rejections above. Wilson et al. does not specifically disclose quantitating a DNA sample by comparing the detected result with a result from a standard DNA.

Wang et al. disclose a method for the quantitation of mRNA through a PCR amplification wherein the reaction product is compared to an internal standard curve used for quantitating the specific target mRNAs (Page 9718, Column 1, Paragraphs 2,3, Column 2, Paragraph 3; Pages 9719, Figure 2).

Wang et al. clearly demonstrates that quantitation of a DNA sample through comparison to a standard DNA sample was well within the knowledge of one of ordinary skill at the time of invention. It would have been *prima facie* obvious to one of skill in the art at the time of invention to practice the methods as claimed.

Allowable Subject Matter

Regarding Claims 3, 5, 7, 8, 11, and 25, a search of the art revealed no prior art teaching or suggesting the amplification the *AluSTXa* or *ALUSTYa* locus for use in a gender determination assay. Claim 3, 5, 7, 8, 11, and 25 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding Claims 4, 6, 7, and 26, a search of the appropriate sequence databases and relevant textual art revealed no prior art teaching or suggesting the instant primer sequences for use in the amplification of the *AluSTXa* or *ALUSTYa* locus in a gender determination assay. Claims 4, 6, and 26 are rejected due to their dependence on a rejected claim.

Conclusion

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CMB



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

9/19/05